JUL 2 6 2012

510(k) Summary Pursuant to 21 CFR 807.92

K110898 **Date of preparation: 5 July 2012**

1. Submitted By: AmMed Surgical Equipment, LLC
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   Tampa, Florida 33619

2. Contact: David C. Furr
   FDC Services, LLC
   8708 Capehart Cove
   Austin, Texas 78733
   512-906-9654

3. Product: S.C.O.R.E.S Units, Self Contained Operating Room Equipment Sterilization Containers
   Regulation: 880.6850, Sterilization Wrap
   Class II
   Product Code: KCT

4. Common/Trade Name:
   S.C.O.R.E.S Units

   Sterilization Wrap/Container

Description:

The S.C.O.R.E.S. Unit (self contained operating room equipment sterilization unit) is a sterilization container and delivery system capable of holding multiple instrument sterilization trays. The S.C.O.R.E.S. container can be loaded with multiple surgical instrument trays needed for a single surgery, steam sterilized, dried in the chamber drying cycle, removed from the autoclave on a transport cart, stored for up to 30 days, and delivered to the surgical suite for opening and use of the contents. The system includes the S.C.O.R.E.S. cabinet with wheels for loading into sterilizers, internal shelves for placement of sterilization trays, a filter system to allow steam penetration and maintain sterility, and an adjustable transport cart to allow for movement of the loaded system.

Instrument trays within the S.C.O.R.E.S Unit do not need to be placed in sterilization containers or wrapped to maintain sterile integrity as the filtered Unit does so. Once opened in the surgical suite and the contents are to be used immediately. The subject device has been extensively tested, and verified to perform in a safe and effective manner.

Intended Use:

The SCORES® Sterilization Container is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit must be used with the SCORES® transfer cart, SCORES® filters, and integrity locks.

The unit is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270° and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray.

The SCORES® Unit was tested and validated with rigid instruments containing lumens with an inner diameter of 3.8mm and an overall length of 370mm. Do not use with instruments containing lumens with an inner diameter smaller than 3.8mm and an overall length longer than 370mm.

Use only uncovered, perforated or wire mesh general delivery trays within the SCORES® Sterilization Container.

Technological Characteristics:

The S.C.O.R.E.S. Unit is a sterilization cabinet constructed from stainless steel and provided with a filtration system.

The Unit can be loaded with all of the instrumentation needed for a surgical case. Instruments are placed into trays, which need not be wrapped. Individual trays of instruments should weigh no more than 25lbs. and up to 12 trays can be arranged on the shelves of the S.C.O.R.E.S. Unit. The loaded unit has a filtration system to allow for steam penetration.

The wheeled Unit is transported on an adjustable cart, which can be adjusted to the height of a prevacuum autoclave chamber. The sealed, loaded unit can be rolled into the chamber and processed in a normal cycle.

The S.C.O.R.E.S. Unit has been validated in accordance with relevant industry standards using a hospital steam sterilizer. Validation was done with prevacuum steam half cycles and drying was also accomplished. Validation was done with an Amsco (Steris) Model 3043.

The product has also been shown to be capable of maintaining sterility of the contents for up to 30 days.

Substantial Equivalence:

The S.C.O.R.E.S. Unit has been determined to be substantially equivalent to the Allegiance Genesis Container System. For prevacuum sterilization applications, the predicate device has similar technical features, indications for use, and the safety and effectiveness of the devices is equivalent.

Conclusions:

The predicate devices and the AmMed Surgical S.C.O.R.E.S Unit container system share similar indications, technology, and application. Although the S.C.O.R.E.S. unit holds more equipment, the device is essentially equivalent to the predicate device products in key areas of performance that affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 26 2012

Ammed Surgical Equipment, LLC
C/O Mr. David C. Furr
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8708 Capehart Cove
Austin, Texas 78733

Re: K110898
Trade/Device Name: Scores Unit Sterilization Container
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: July 5, 2012
Received: July 13, 2012

Dear Mr. Furr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K110898

Device Name: SCORES® Unit Sterilization Container

Indications for Use:

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Prescription Use____ or Over-the-counter use _X__
(per CFR 801.109)

Concurrence of CDRH

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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